UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,680	08/20/2003	Kevin J. Frank	5074A-000064	6450

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ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

	Application No.	**Applicant(s)**
Office Action Summary	10/644,680	FRANK ET AL.
	Examiner	**Art Unit**	
	Jeffrey S. Smith	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>23 March 2007</u>.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>1-42</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-42</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>20 August 2003</u> is/are: a)☐ accepted or b)☒ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>10/03 07/04 09/06</u>.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application

6)☐ Other: _____ .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse is acknowledged. This is found persuasive therefore the Examiner withdraws the election requirement.

Information Disclosure Statement

Applicant has cited 738 references in the information disclosure statements. The Examiner is only able to review the title of the 738 references to determine whether further scrutiny is justified, given the number of references and the practical constraints of the examination procedure. Therefore unless otherwise cited in this Office action, the only portion of each of the cited references that is considered is the title. All of the references used in the rejections below are from the information disclosure statements.

If applicant desires to have specific sections of specific references considered, then applicant should identify the references and the sections of the references that are relevant to specific claim elements. This identification by applicant will be helpful to applicant in avoiding an inference of burying, which is a submission of a highly material reference in a long list of less relevant references. Burying has long been explicitly discouraged by the M.P.E.P. and burying may lead to an inference of inequitable conduct, *Golden Valley Microwave Foods v. Weaver Popcorn*, 837 F.Supp. 1444 (N.D. Ind. 1992); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp. 948 (S.D. Fla. 1972). "It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If

a long list is submitted, highlight those documents which have been specifically brought

to applicant's attention and/or are known to be of most significance." M.P.E.P. 2004.

For example, if applicant is aware of references that definitely disclose or at least

are relevant to acquiring first patient orientation information, then applicant should

identify a reference that best discloses or relates to this feature, or if applicant is unable

to select the best reference, then identify the section of each reference that discloses or

is relevant to this feature. Similarly, if applicant is aware of references that disclose or

are relevant to generating a digitally reconstructed radiograph using three-dimensional

image data and patient orientation information, then applicant should identify either the

best reference or the section of each reference that discloses this feature. As another

example, if applicant is aware of references that disclose or are relevant to performing

intensity adjustment of the two dimensional image to reduce the effect of an interfering

object, then applicant should identify either the best reference or the section of each

reference that discloses this feature. If applicant is aware of any references that

disclose or are relevant to identifying a center of the body of interest in the first and

second images, then applicant should identify either the best reference or the section of

each reference that discloses this feature. If applicant is aware of references that

disclose or are relevant to aligning the two dimensional image with the digitally

reconstructed radiograph using a similarity measure or a cost measure, then applicant

should identify either the best reference or the section of each reference that discloses

this feature. These examples are given as a guide to applicant, if applicant believes

that one or more references are relevant or material to the patentability of other features

as well, applicant should identify these references.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this

application because the reference arrows in figures 4-19 and 21 are lost in the

background shade which prevents each reference number from identifying its element.

Applicant is advised to employ the services of a competent patent draftsperson outside

the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings.

The corrected drawings are required in reply to the Office action to avoid abandonment

of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by G. Penney et

al. "Validation of a two- or three-dimensional registration algorithm for aligning

preoperative CT images and intraoperative fluoroscopy images" ("Penney").

Penney discloses a method for registering two-dimensional image data with

three-dimensional image data of a body of interest (abstract), said method comprising:

acquiring the three-dimensional image data having first patient orientation information

(abstract); acquiring the two-dimensional image data having second patient orientation

information (abstract); and generating a digitally reconstructed radiograph that

substantially corresponds to the two-dimensional image data using the three-

dimensional image data and the first and second patient orientation information

(abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Penney in view of the Series 9600 Mobile Digital Imaging System.

Penney discloses a PA view and a RAO view as shown in figure 2. The Series

9600 discloses a device for acquiring a two-dimensional anterior to posterior image and

a two-dimensional lateral image. It would have been obvious to one of ordinary skill in

the art at the time of invention to use the 9600 to acquire the digital images for the

benefit of generating a DRR which aids in treating patients as taught by Penney on

page 1024.

For claim 3, Penney discloses identifying a center of a body of interest in the two-dimensional anterior to posterior image and the two-dimensional lateral image as discussed on page 1029.

For claim 4, Penney discloses generating a digitally reconstructed radiograph further includes generating an anterior to posterior digitally reconstructed radiograph and a lateral digitally reconstructed radiograph corresponding to the two-dimensional anterior to posterior image and the two-dimensional lateral image as discussed in section 2.

For claim 5, Penney discloses identifying a center of the body of interest in the anterior to posterior digitally reconstructed radiograph and the lateral digitally reconstructed radiograph as discussed in section 2.

For claim 6, Penney discloses identifying a common point in the three-dimensional image data with the two-dimensional image data using the identified centers of the anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image and lateral digitally reconstructed radiograph image as shown in figure 2.

For claim 7, Penney discloses refining the registration of the two-dimensional image data with the three-dimensional image data using the first and second patient orientation information and the common point information as shown in figure 2.

For claim 8, Penney discloses the refined registration employs at least two similarity/cost measures selected from a group of at least a normalized mutual information algorithm, a mutual information algorithm, a gradient difference algorithm, a

gradient algorithm, a line contour algorithm, a surface contour algorithm, a pattern intensity algorithm or a combination thereof as discussed on page 1025.

For claim 9, Penney discloses optimizing the selected similarity/cost measures using an optimization algorithm selected from a group of at least a multi-stage steepest ascent algorithm, a steepest ascent algorithm, a gradient-based optimization algorithm or a combination thereof on page 1025.

For claim 10, Penney discloses adjusting a registration window on the body of interest in each anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image, and lateral digitally reconstructed radiograph image, wherein only the image data within the registration windows are used for refined registration as discussed in section 2.

For claim 11, Penney discloses verifying the refined registration for accuracy by selecting a point in the three-dimensional image data to confirm its accuracy with a point in the two-dimensional image data as shown in figure 2.

For claim 14, Penney discloses performing multiple registrations on multiple bodies of interest.

For claim 15, Penney show the body of interest is a vertebrae.

Claims 12-13 and 16-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney in view of Series 9600 as applied to claims 2-11 above, and further in view of Penney et al. "A Comparison of Similarity Measures for Use in 2-D-3-D Medical Image Registration" ("Penney II").

For claim 12, Penney II shows performing a refinement registration utilizing normalized mutual information and pattern intensity as discussed in section 3. It would have been obvious to one of ordinary skill in the art at the time of invention to use the similarity measures of Penney II when generating the DRR of Penney for the benefit of increasing the accuracy of registration as taught by Penney II in the abstract.

For claim 13, Penney II discloses optimizing the refinement registration by utilizing a multi-stage steepest ascent algorithm.

For claim 16, Penney and Series 9600 disclose acquiring the three-dimensional image data; acquiring the two-dimensional image data; Penney discloses generating a digitally reconstructed radiograph using the three-dimensional image data; and Penney II discloses registering the two-dimensional image data with a three-dimensional image data using a first similarity/cost measure and a second similarity/cost measure (the specification defines similarity/cost measure as either a similarity measure or a cost measure, which means that the several similarity measures used in Penney II in section 3 read on this element).

For claim 17, Penney II discloses minimizing the difference between the digitally reconstructed radiograph and the two-dimensional image data.

For claim 18, Penney II discloses optimizing the first similarity/cost measure and the second similarity/cost measure.

For claim 19, Penney II discloses the first similarity/cost measure is normalized mutual information and the second similarity/cost measure is pattern intensity.

For claim 20, Penney II discloses optimizing the normalized mutual information and the pattern intensity utilizing a multi-stage steepest ascent algorithm.

For claim 21, Penney and Penney II disclose verifying registration accuracy.

For claim 22, Penney discloses adjusting a registration window in the two-dimensional image data and a registration window in the digitally reconstructed radiograph where the image data within the registration windows are used for registration.

For claim 23, Penney and Penney II disclose acquiring three-dimensional image data further includes acquiring three-dimensional image data having first patient orientation information and wherein acquiring two-dimensional image data further includes acquiring two-dimensional image data having second patient orientation information and wherein generating the digitally reconstructed radiograph further includes using the first and second patient orientation information.

Claims 24-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penney, Series 9600 and Penney II as applied to claims 16-23 above, and further in view of B. Schueler et al. "Correction of image intensifier distortion for three-dimensional x-ray angiography."

For claim 24, Schueler discloses performing intensity adjustment on the image data (abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to perform intensity adjustment on the images of Penney for the benefit of improving accuracy as taught by Schueler in the abstract.

For claim 25, Schueler discloses performing intensity adjustment and Penney discloses generating a digitally reconstructed radiograph further includes generating a lateral digitally reconstructed radiograph that substantially corresponds to the two-dimensional lateral image.

For claim 26 Penney and Penney II disclose aligning the two-dimensional lateral image with the lateral digitally reconstructed radiograph utilizing at least one similarity/cost measure.

For claim 27 Penney II discloses that the similarity/cost measure is normalized mutual information.

For claim 28, Penney and Series 9600 disclose acquiring the three-dimensional image data of the body of interest; acquiring a two-dimensional image of the body of interest; Penney discloses generating a digitally reconstructed radiograph that substantially corresponds to the two-dimensional image; Schueler discloses performing intensity adjustment of the two-dimensional image to reduce the effect of an interfering object; and Penney and Penney II disclose aligning the two-dimensional image with the digitally reconstructed radiograph using a similarity/cost measure.

For claim 29, Penney discloses the two-dimensional image of the body of interest is a two-dimensional lateral image.

For claim 30, Penney discloses acquiring a two-dimensional anterior to posterior image and generating an anterior to posterior digitally reconstructed radiograph that substantially corresponds to the anterior to posterior image.

For claim 31, Penney and Penney II disclose registering the two-dimensional lateral image and the two-dimensional anterior to posterior image with the three-dimensional image data using a first similarity/cost measure and a second similarity/cost measure.

For claim 32, Penney and Penney II disclose acquiring the three-dimensional image data further includes acquiring first patient orientation information, wherein acquiring the two-dimensional lateral image and the two-dimensional anterior to posterior image further includes acquiring second patient orientation information, and wherein generating the digitally reconstructed radiographs further includes generating the lateral digitally reconstructed radiograph and the anterior to posterior digitally reconstructed radiograph using the three-dimensional image data and the first and second patient orientation information.

For claim 33 Penney discloses identifying a center of the body of interest in the two-dimensional anterior to posterior image and the two-dimensional lateral image.

For claim 34 Penney discloses identifying a center of the body of interest in the anterior to posterior digitally reconstructed radiograph and the lateral digitally reconstructed radiograph.

For claim 35 Penney discloses identifying a common point in the three-dimensional image data with the two-dimensional image data using the identified centers of the anterior to posterior image, lateral image, anterior to posterior digitally reconstructed radiograph image and lateral digitally reconstructed radiograph image.

For claim 36 Penney and Penney II disclose optimizing the first and second similarity/cost measures using an optimization algorithm.

For claim 37 Penney and Series 9600 disclose acquiring the three-dimensional image data having first patient orientation information; acquiring a first two-dimensional image having second patient orientation information; acquiring a second two-dimensional image having third patient orientation information; Penney discloses identifying a center of the body of interest in the first and second images; Penney discloses generating first and second digitally reconstructed radiographs; Penney discloses identifying the center of the body of interest in the first and second digitally reconstructed radiographs; and Penney and Penney II disclose registering the first and second two-dimensional images with the three-dimensional image data using at least a first similarity/cost measure and a second similarity/cost measure.

For claim 38 Penney discloses first two-dimensional image is a first two-dimensional anterior to posterior image and said second two-dimensional image is a second two-dimensional lateral image.

For claim 39 the combination of Schueler and Penney discloses performing intensity adjustment on the two-dimensional lateral image and aligning the two-dimensional lateral image with the lateral digitally reconstructed radiograph.

For claim 40 Penney II discloses the first similarity/cost measure is normalized mutual information and the second similarity/cost measure is pattern intensity.

For claim 41 Penney and Penney II disclose optimizing the first and second similarity/cost measures.
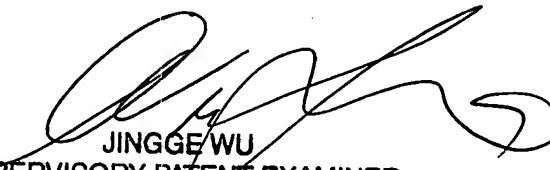
For claim 42 Penney and Penney II disclose first and second similarity/cost measures are optimized using a multi-stage steepest ascent algorithm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Smith whose telephone number is 571 270-1235. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on 571 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSS
July 5, 2007

JINGGE WU
SUPERVISORY PATENT EXAMINER